



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS)

National Institutes of Health

Submission for OMB review; 30-day comment request

NIMH Database of Cognitive Training and Remediation Studies (DCTRS) (NIMH)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on April 15, 2014, pages 21250-21252 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-

6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Keisha Shropshire, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301-443-4335 or E-mail your request, including your address to: nimhprapubliccomments@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION

NIMH Database of Cognitive Training and Remediation Studies (DCTRS) – New – National Institute of Mental Health (NIMH), National Institute of Health (NIH).

Need and Use of Information Collection: The NIMH Database of Cognitive Training and Remediation Studies (DCTRS) is an integrated database that includes study- and subject-level data from studies of cognitive remediation (CR) in schizophrenia. DCTRS will allow NIMH staff and interested investigators to examine the ways in which various patient characteristics, intervention approaches and features, and treatment combinations affect responses to remediation. The DCTRS Study Information Form and Data

Submission Agreement are necessary for the “Submitter” to request permission to submit study data to the NIMH DCTRS for general research purposes. The primary use of this information is to collect submitter information and study information for inclusion in the NIMH DCTRS database. The DCTRS data submission agreement includes two forms: 1) the data submission form that includes the terms, agreement, submitter information and certifications, and 2) the study information form which collects de-identified data for each study.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 60.

Estimated Annualized Burden Hours

Form	Type of Respondent	Number of Respondents	Frequency of Response	Average time per response (in hours)	Annual hour burden
Data Submission Agreement	Principal Investigators/Physicians	12	1	5	60

Dated: September 29, 2014.

Keisha Shropshire,
NIMH Project Clearance Officer,
NIMH, NIH.

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